MAY 2 6 2009

Attachment B

Summary of Safety and Effectiveness Prepared in accordance with 21 CFR Part 807.92(c).



GE Healthcare

GE Medical Systems (China) Co., Ltd

No. 19 Changjiang Road, National Hi-Tech Development Zone

Wuxi, Jiangsu Province, CHINA 214028

Section a):

Submitter: GE Medical Systems (China) Co., Ltd.

No. 19 Changjiang Road, National Hi-Tech Development Zone, Wuxi, Jiangsu Province,

CHINA 214028

Contact Person: Yalan Wu,

Manager, Safety and Regulatory

Telephone: 86-510-85278652; Fax: 86-510-85227347

Date Prepared: April 20, 2009

2. Device Name: GE LOGIQ i/e, Vivid e Ultrasound

Ultrasonic Pulsed Echo Imaging System, 21 CFR 892.1560, 90-IYO Ultrasonic Pulsed Doppler Imaging System, 21 CFR 892.1550, 90-IYN

Diagnostic Ultrasonic Transducer, 21 CFR 892.1570, 90-ITX

Marketed Device: GE LOGIQ-i/e & Vivid-e Compact Ultrasound, 510(k) No: K072797

(90-IYO/IYN/ITX) A device currently in commercial distribution.

GE Venue 40 Compact Ultrasound, 510(k) No: K091164

(90-IYO/IYN/ITX) A device currently cleared and starting to commercial distribution.

- 4. Device Description: The GE Compact Ultrasound is a very compact and portable diagnostic ultrasound system having three variations: LOGIQ i, LOGIQ e and Vivid e, each with options and features suited for its market niche. It has an integrated keyboard, LCD display and several interchangeable electronic-array transducers with an approximate size of 34 cm wide, 29 cm deep and 6 cm high in transport configuration and provides digital acquisition, processing and display capability. The user interface includes a computer keyboard, an intuitive layout of specialized controls, color GUI display and Doppler audio.
- 5. Indications for Use: The subject modified device is a general purpose ultrasound system intended for use by a qualified physician for evaluation by ultrasound imaging or fluid flow analysis of the human body. Specific clinical applications and exam types include: Fetal/OB; Abdominal (GYN & Urology); Pediatric; Small Organ (breast, testes, thyroid); Neonatal and Adult Cephalic; Cardiac (adult & pediatric); Peripheral Vascular; Intra-operative (abdominal, thoracic and PV), Musculo-skeletal Conventional & Superficial, Transrectal and Transvaginal, and Thoracic/Pleural for motion/sliding and fluid detection.
- 6. Comparison with Predicate Device: The modified device is of a comparable type and substantially equivalent to the current GE LOGIQ e and Venue 40 with overall performance in a small and compact package. It has the same overall characteristics, key safety and effectiveness features, physical design, general overall construction, and materials. And all technological characteristics and safety and effectiveness features are equivalent.

Section b):

- 1. Non-clinical Tests: The device has been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness, electromagnetic compatibility, as well as thermal, electrical and mechanical safety, and has been found to conform with applicable medical device safety standards.
- 2. Clinical Tests: None required.
- 3. <u>Conclusion</u>: Intended uses and other key features are consistent with traditional clinical practice, FDA guidelines, and established methods of patient examination. The design and development process of the manufacturer conforms with 21 CFR 820, ISO 9001:2000 and ISO 13485 quality systems. The device conforms to applicable medical device safety standards and compliance is verified through independent evaluation with ongoing factory surveillance. Diagnostic ultrasound has accumulated a long history of safe and effective performance. Therefore, it is the opinion of GE Healthcare that the GE LOGIQ i/e Vivid e Ultrasound imaging device is substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.



MAY 26 2009

Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

GE Medical Systems, Ultrasound and Primary Care Diagnostics, LLC % Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K091374

Trade/Device Name: GE LOGIQ i/e & Vivid e Compact Ultrasound System

Regulation Number: 21 CFR 892.1550

Regulation Name: Ultrasonic pulsed doppler imaging system

Regulatory Class: II

Product Code: IYN, IYO, and ITX

Dated: May 8, 2009 Received: May 11, 2009

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the GE LOGIQ i/e & Vivid e Compact Ultrasound System, as described in your premarket notification:

Transducer Model Number

<u>4C-RS</u>	<u>9L-RS</u>	<u>i/t739-RS</u>
8C-RS	<u>12L-RS</u>	<u>3S-RS</u>
E8C-RS	<u>16L-RS</u>	<u>6S-RS</u>
<u>8L-RS</u>	<u>i12L-RS</u>	<u>P2D</u>

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the <u>Federal Register</u>.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

If you have any questions regarding the content of this letter, please contact Lauren Hefner at (240) 276-3666.

Sincerely yours,

Janine M. Morris

Acting Director, Division of Reproductive, Abdominal, and Radiological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure(s)

Indications for Use

510(k) Number (if known): <u>K091374</u>
Device Name: GE LOGIQ i/e & Vivid e Compact Ultrasound
Indications For Use:
The LOGIQ i/e & Vivid e is a general purpose ultrasound system intended for use by a qualified physician for evaluation by ultrasound imaging or fluid flow analysis of the human body. Specific clinical applications and exam types include: Fetal/OB; Abdominal (GYN & Urology); Pediatric; Small Organ (breast, testes, thyroid); Neonatal and Adult Cephalic; Cardiac (adult & pediatric); Peripheral Vascular; Intra-operative (abdominal, thoracic and PV), Musculoskeletal Conventional & Superficial, Transrectal and Transvaginal, and Thoracic/Pleural for motion/sliding and fluid detection.
Prescription Use X AND/OR Over-The-Counter Use (Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C) (PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)
(Division Sign-Off) Division of Reproductive, Abdominal and Radiological Devices 510(k) Number (1374)

GE Compact Ultrasound System

LOGIQ i, LOGIQ e, Vivid e

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

					Mode	e of Ope	ration				
Clinical Application Anatomy/Region of Interest	В.	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler			Harmonic Imaging	Coded Pulse	Othe
Ophthalmic											
Fetal / Obstetrics	P	Р	P	Р	Р	Р	Р	P	Р	Р	ļ
Abdominal ^[1]	Р	P	Р_	Р	Р	P	Р	P	Р	Р	
Pediatric	Р	Р	P	Р	P	Р	Р	Р	Р_	Р	
Small Organ ^[2]	Р	Р	Р		Р		Р	P	P	Р	
Neonatal Cephalic	Р	Р	Р	Р	Р	Р	P	Р	Р	Р	
Adult Cephalic	Р	P	Р	P	Р	р.	Р	Р	Р	Р	
Cardiac ^[3]	Р	Р	Р	Р	Р	Р	Р	Р	P	Р	
Peripheral Vascular	Р	Р	Р	P	Р		Р	P	Р	Р	<u> </u>
Musculo-skeletal Conventional	Р	P	Р		Р		P	P	Р	Р	
Musculo-skeletal Superficial	N_	N	N		N		N	N	N	N	
Thoracic/Pleural (specify) [4]	N	N	N	N_	N	N ·	N	N	N	N	
Other ^[5]	₽	Р	Р	Р	Р	Р	Р	P	Р	Р	
Exam Type, Means of Access					<u> </u>						<u> </u>
Transesophageal			<u> </u>		ļ						<u> </u>
Transrectal	Р	· P	P		Р	<u> </u>	P	Р	Р		<u> </u>
Transvaginal	Р	Р	Р		P		P	Р	P		<u> </u>
Transuretheral								<u> </u>			<u> </u>
Intraoperative	Р	Р	P		Р		P	Р	P	Р	Ļ
Intraoperative Neurological											
Intravascular						<u> </u>			ļ	<u> </u>	<u> </u>
Laparoscopic			-			1	<u> </u>	1			

Laparoscopic				<u> </u>			1		1	
N = new indication; P = pr Notes: [1] Abdominal incl [2] Small organ incl [3] Cardiac is Adu [4] For detection of [5] Other use inclu [*] Combined mod [*] Coded Pulse is	udes GYN and U cludes breast, te It and Pediatric. If fluid and pleura Ides Urology/Pro les are B/M, B/P	Jrological stes, thyroid. al motion/slidin state WD, B/Color/F	ng; PWD, B/Po	(Div Divi Rad	ision Si sion of l	Reprod	luctive, <i>l</i> ces	Abdomin		
	(PLEASE DO NOT WR	ITE BELOW THIS LI					D)			

Prescription User (Per 21 CFR 801.109)

(Division Sign-Off) Division of Reproductive, Abdominal and Radiological Devices K091374

510(k) Number _

GE Compact Ultrasound with 4C-RS Transducer

LOGIQ i, LOGIQ e, Vivid e

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

		Mode of Operation									
Clinical Application Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler		Combined Modes	Harmonic Imaging	Coded Pulse*	Other
Ophthalmic									,		
Fetal / Obstetrics	P	Р	P		Р_		Р	P	P	Р	
Abdominal ^[1]	Р	Р	Р		Р		Р	Р	Р	P	
Pediatric	Р	₽	P		Р		Р	Р	P	P	
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic											
Cardiac ^[3]											
Peripheral Vascular								,			
Musculo-skeletal Conventional											
Musculo-skeletal Superficial	·										<u> </u>
Thoracic/Pleural (specify) [4]	N	N	N		N		N	N	N	N.	
Other ^[5]	Р	Р	Р		Р		Р	Р	Р	Р	
Exam Type, Means of Access							<u> </u>				
Transesophageal							Į				
Transrectal		, ,									
Transvaginal											
Transuretheral											
Intraoperative (specify)											<u> </u>
Intraoperative Neurological									•		
Intravascular											
Laparoscopic											

Notes:	[1]	Abdomina	l includes	GYN and	Urological
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- [2] Small organ includes breast, testes, thyroid.
- [3] Cardiac is Adult and Pediatric.
- [4] For detection of fluid and pleural motion/sliding;
- [5] Other use includes Urology/Prostate
- [*] Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD.
- [*] Coded Pulse is for digitally encoded harmonics.

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(PLEASE DO NOT WRITE BELOW	/ THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CD	RH, Office of Device Evaluation (ODE)
	(Division Sign-Off)
	Division of Reproductive, Abdominal and
Prescription User (Per 21 CFR 801.109)	Radiological Devices 510(k) Number

GE Compact Ultrasound with 8C-RS Transducer

LOGIQ i, LOGIQ e, \dot{V} ivid e

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation										
Clinical Application Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other
Ophthalmic											
Fetal / Obstetrics											
Abdominal ^[1]	Р	Р	P		Р		Р	Р	Р		
Pediatric	Р	Р	Р		Р		Р	Р	P		
Small Organ (specify)	Р	P	P		Р		Р	P	P		
Neonatal Cephalic	Р	Р	P		Р		Р	Р	P		
Adult Cephalic											
Cardiac ^[3]	Р	P	Р		Р		Р	Р	Р		
Peripheral Vascular	P	P	Р		Р		Р	Р	Р		
Musculo-skeletal Conventional	Р	Р	Р		Р		P	Р	Р		
Musculo-skeletal Superficial											
Thoracic/Pleural (specify)[4]	N	N	N		N		N	N	N		
Other ^[5]											
Exam Type, Means of Access											
Transesophageal										<u> </u>	
Transrectal										<u> </u>	
Transvaginal					ļ		ļ .				
Transuretheral -											
Intraoperative (specify)				<u> </u>							
Intraoperative Neurological											
Intravascular											
Laparoscopic											

١	N = new indication; P = previous!	v cleared by FDA:	E = added under	Appendix E

Notes:	[1]	Abdominal	includes	GYN	and	Urological
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- [2] Small organ includes breast, testes, thyroid.
- [3] Cardiac is Adult and Pediatric.
- [4] For detection of fluid and pleural motion/sliding;
- [5] Other use includes Urology/Prostate
- [*] Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD.
- [*] Coded Pulse is for digitally encoded harmonics.

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Concurrence of CD	RH, Office of Device Evaluation (ODE)
	(Division Sign-Off)
	Division of Reproductive, Abdominal and
Prescription User (Per 21 CFR 801.109)	Radiological Devices 510(k) Number <u> </u>

GE Compact Ultrasound with E8C-RS Transducer

LOGIQ i, LOGIQ e, Vivid e

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

					Mode	of Ope	eration				
Clinical Application Anatomy/ Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	
Ophthalmic											
Fetal / Obstetrics	Р	P	P		P		Р	Р	Р		
Abdominal ^[1]	Р	Р	P		Р	· ·	Р	Р	P		
Pediatric											
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic	•										
Cardiac											
Peripheral Vascular					<u> </u>			<u>'</u>			
Musculo-skeletal Conventional					<u></u>		ļ				
Musculo-skeletal Superficial											<u> </u>
Thoracic/Pleural (specify)[4]											<u> </u>
Other ^[5]	Р	Р	P		Р		Р	P	P		
Exam Type, Means of Access											Ŀ
Transesophageal							,				ļ
Transrectal	P	P	P		P		P	Р	Р		
Transvaginal	Р	P	P		Р		Р	P	Р		<u> </u>
Transuretheral											
Intraoperative (specify)				_							
Intraoperative Neurological											
Intravascular											
Laparoscopic			1	į		1					

Notes: [1] Abdominal	includes	GYN	and	Uroloa	iical
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- [2] Small organ includes breast, testes, thyroid.
- [3] Cardiac is Adult and Pediatric.
- [4] For detection of fluid and pleural motion/sliding;
- · [5] Other use includes Urology/Prostate
- [*] Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD. [*] Coded Pulse is for digitally encoded harmonics.

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Concurrence of CDI Prescription User (Per 21 CFR 801.109)	(Division Sign-Off) (Division of Reproductive, Abdominal and Radiological Devices 510(k) Number

GE Compact Ultrasound with 8L-RS Transducer

LOGIQ i, LOGIQ e, Vivid e

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation										
Clinical Application Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler		Harmonic Imaging	Coded Pulse*	Othe
Ophthalmic											ļ
Fetal / Obstetrics						ļ		ļ			<u> </u>
Abdomina! ^[1]	Р	Р	Р		Р		P	P	Р	Р	
Pediatric	<u>P</u>	Р	Р.		Р		Р	Р	Р	Р	ļ <u>.</u>
Small Organ (specify) ^[2]	P	Р	Р		Р		P	Р	Р	Р	<u> </u>
Neonatal Cephalic						ļ		ļ		ļ	ļ
Adult Cephalic						<u>.</u>		ļ			—
Cardiac ^[3]	P	Р	P		P		P	P	Р		<u> </u>
Peripheral Vascular	Р	P	Р		Р	<u> </u>	Р	P	Р	Р	<u> </u>
Musculo-skeletal Conventional	Р	P	Р		Р		P	P	Р		ļ
Musculo-skeletal Superficial					<u> </u>	ļ. <u></u>	<u> </u>	<u> </u>		<u> </u>	
Thoracic/Pleural (specify)[4]				ļ						<u> </u>	—
Other ^[5]			<u> </u>		ļ	ļ	ļ	ļ			
Exam Type, Means of Access						<u> </u>					
Transesophageal			<u> </u>			ļ <u> </u>	<u></u>	ļ		ļ	<u> </u>
Transrectal		٠				<u> </u>				<u>.</u>	ـــــ
Transvaginal		<u> </u>	ļ	ļ		ļ			ļ	ļ·	_
Transuretheral			ļ	<u> </u>	<u> </u>	ļ	<u> </u>		-	<u> </u>	1
Intraoperative (specify)[5]	Р	Р	P	<u> </u>	Р		Р	Р	P		—
Intraoperative Neurological		$oxed{oxed}$		ļ			1	ļ	<u> </u>	 	
Intravascular		ļ	ļ						ļ	<u> </u>	\bot
Laparoscopic					I					<u> </u>	

No	tes:	[1]	Abdominal includes GYN and Urological	
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- [2] Small organ includes breast, testes, thyroid.
- [3] Cardiac is Adult and Pediatric.
- [4] For detection of fluid and pleural motion/sliding;
- [5] Other use includes Urology/Prostate
- [*] Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD.
- [1] Coded Pulse is for digitally encoded harmonics.

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Concurrence	of CDRH, Office of Device Evaluation (ODE)
	(Division Sign-Off)
	Division of Reproductive, Abdominal and
Prescription User (Per 21 CFR 801.109)	Radiological Devices

GE Compact Ultrasound with 9L-RS Transducer

LOGIQ i, LOGIQ e, Vivid e

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation										
Clinical Application Anatomy/Region of Interest	В	M .	PW Doppler	CW Doppler	Color Doppler	Color M Doppler		Combined Modes	Harmonic Imaging	Coded Pulse	Other
Ophthalmic											
Fetal / Obstetrics			<u> </u>								
Abdominal ^[1]	Р	Р	P		Р		Р	Р	Р	P	
Pediatric	Р	Р	Р		Р		P	Р	Р	Р	
Small Organ (specify) ^[2]	Р	₽	P		Р		Р	Р	Р	P	
Neonatal Cephalic									-		
Adult Cephalic											
Cardíac ^[3]											
Peripheral Vascular	Р	P	Р		P		Р	P	Р	Р	
Musculo-skeletal Conventional	Р	Р	Р		Р		P	Р	Р	·P	
Musculo-skeletal Superficial											
Thoracic/Pleural (specify) [4]											
Other ^[5]											
Exam Type, Means of Access											
Transesophageal				ļ				<u> </u>			
Transrectal			<u> </u>			ļ					ļ
Transvaginal										ļ	ļ
Transuretheral				<u> </u>							
Intraoperative (specify) ^[5]	P	Р	Р		Р		Р	P	Р	P	
Intraoperative Neurological											
Intravascular										,	
Laparoscopic				<u> </u>							<u> </u>

Notes:	[1]	Abdominal	includes	GYN	and	Urological
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- [2] Small organ includes breast, testes, thyroid.
- [3] Cardiac is Adult and Pediatric.
- [4] For detection of fluid and pleural motion/sliding;
- [5] Other use includes Urology/Prostate
- [*] Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD.
- [*] Coded Pulse is for digitally encoded harmonics.

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Concurrence of C	DRH, Office of Device Evaluation (ODE)
Prescription User (Per 21 CFR 801.109)	(Division Sign-Off) Division of Reproductive, Abdominal and Radiological Devices 510(k) Number

GE Compact Ultrasound with 12L-RS Transducer

LOGIQ i, LOGIQ e, Vivid e

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

							· · · · · · · · · · · · · · · · · · ·				
		Mode of Operation									
Clinical Application Anatomy/Region of Interest	В	М	PW Doppler	Doppler CW	Color Doppler	Color M Doppler	Power Doppler		Harmonic Imaging	Coded Pulse	
Ophthalmic											
Fetal / Obstetrics											
Abdominal											
Pediatric	P	Р	Р		Р		P	Р	Р	Р	
Small Organ ^[2]	Р	Р	Р		P		Р	P	Р	Р	
Neonatal Cephalic								<u> </u>			
Adult Cephalic								,			
Cardiac						ļ					
Peripheral Vascular	P	Р	P		Р		P	Р	Р	Р	
Musculo-skeletal Conventional	Р	Р	P		P		Р	Р	P	Р	
Musculo-skeletal Superficial	N	N	N		N		N	N	N	N	
Thoracic/Pleural (specify)[4]	N	N	N		N		N	N	N	N	<u></u>
Other (specify) [5]											
Exam Type, Means of Access							ļ				
Transesophageal											<u> </u>
Transrectal							<u> </u>			ļ <u>.</u>	
Transvaginal								ļ			ļ
Transuretheral			<u> </u>			<u> </u>		ļ	<u> </u>	ļ	
Intraoperative (5) (specify)				<u> </u>	ļ	<u> </u>			<u> </u>	ļ	<u> </u>
Intraoperative Neurological				<u> </u>	<u> </u>				<u> </u>		
Intravascular		<u> </u>	<u> </u>		<u> </u>		ļ	<u> </u>			
Laparoscopic		<u> </u>	<u> </u>				l	<u> </u>		<u> </u>	

Notes:	[1]	l Abdomina!	includes	GYN and	Urological
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- [2] Small organ includes breast, testes, thyroid.
- [3] Cardiac is Adult and Pediatric.
- [4] For detection of fluid and pleural motion/sliding;
- [5] Other use includes Urology/Prostate
- [*] Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD.
- [9] Coded Pulse is for digitally encoded harmonics.

(PLEASE DO NOT WRITE BELOW THIS LINE	E - CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Offi	ce of Device Evaluation (ODE)
Prescription User (Per 21 CFR 801.109)	(Division Sign-Off) Division of Reproductive, Abdominal and Radiological Devices 510(k) Number 91374

GE Compact Ultrasound with 16L-RS Transducer

LOGIQ i, LOGIQ e, Vivid e

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation										
Clinical Application Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler		Combined Modes	Harmonic Imaging	Coded Pulse	
Ophthalmic											
Fetal / Obstetrics											
Abdominal		_									
Pediatric	E	E	E		E		E	E	E	Е	
Small Organ ^[2]	E	E	E		E		ıΕ	E	Ε	Ε	
Neonatal Cephalic											
Adult Cephalic •								_			
Cardiac		-	<u> </u>								
Peripheral Vascular	E	E	E		E		E	E	E	E	
Musculo-skeletal Conventional	E	E	E		E		E	E	E	E	
Musculo-skeletal Superficial	N	N	N		N		N	N·	N	N	
Thoracic/Pleural (specify) [4]										<u> </u>	
Other (specify) ⁽⁵⁾											
Eхат Туре, Means of Access											
Transesophageal											
Transrectal											<u> </u>
Transvaginal											
Transuretheral		_				<u> </u>			<u> </u>	<u> </u>	
Intraoperative [5] (specify)											ļ.,
Intraoperative Neurological							<u></u>				
Intravascular							<u> </u>	ļ			
Laparoscopic											

Notes: [1] Abdominal	includes GYN	and Urological
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- [2] Small organ includes breast, testes, thyroid.
- [3] Cardiac is Adult and Pediatric.
- [4] For detection of fluid and pleural motion/sliding;
- [5] Other use includes Urology/Prostate
- [*] Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD.
- [*] Coded Pulse is for digitally encoded harmonics.

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Concurrence of CDRH,	Office of Device Evaluation (ODE)
Prescription User (Per 21 CFR 801.109)	(Division Sign-Off) Division of Reproductive, Abdominal and Radiological Devices 510(k) Number

GE Compact Ultrasound with i12L-RS Transducer

LOGIQ i, LOGIQ e, Vivid e

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation										
Clinical Application Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler		Harmonic Imaging	Coded Pulse	Other
Ophthalmic											
Fetal / Obstetrics											ļ
Abdominal ⁽¹⁾	Р	Р	P		Р		Р	Р	Р	Р	
Pediatric	Р	Р	Р		Р		Р	Р	P_	P	
Small Organ (specify) ^[2]	Р	P	P		Р		Р	Р	Р	Р	
Neonatal Cephalic										ļ	
Adult Cephalic								1			
Cardiac ^[3]	P.	Р	Р		Р		Р	P	Р		
Peripheral Vascular	Р	P	Р		P		Р	Р	Р	Р	
Musculo-skeletal Conventional	P	P	Р		P		P	P	P_		
Musculo-skeletal Superficial	N	N	N		N		N	N	N.		<u> </u>
Thoracic/Pleural (specify)[4]											
Other ^[5]			<u> </u>								
Exam Type, Means of Access				<u> </u>			<u> </u>	<u></u>			
Transesophageal								<u>.</u>			<u> </u>
Transrectal											<u> </u>
Transvaginal				<u> </u>							
Transuretheral											
Intraoperative (specify) ^[5]	Р	P	Р		P		Р	Р	Р		
Intraoperative Neurological				ļ							
Intravascular			<u> </u>								
Laparoscopic											

Notes:	[1]	Abdominal	includes	GYN	and	Uralog	ical
I TOLOG.	1 1 1		HIGHAGO	\sim \sim \sim	anu		1001

- [2] Small organ includes breast, testes, thyroid.
- [3] Cardiac is Adult and Pediatric.
- [4] For detection of fluid and pleural motion/sliding;
- [5] Other use includes Urology/Prostate
- [*] Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD.
- [*] Coded Pulse is for digitally encoded harmonics.

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Concurrence of CDR	H, Office of Device Evaluation (ODE)
	(Division Sign-Off)
D (C 1 / D 04 OFD 004 400)	Division of Reproductive, Abdominal and
Prescription User (Per 21 CFR 801.109)	Radiological Devices 510(k) Number 16091374
	510(k) Number <u>10091579</u>

GE Compact Ultrasound with i/t739-RS Transducers

LOGIQ i, LOGIQ e, Vivid e

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation										
Clinical Application Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other
Ophthalmic											
Fetal / Obstetrics										 	
Abdominal ^[1]	Р	Р	Р		Р		P	Р	Р		
Pediatric	Р	Р	Р		Р		Р	Р	Р		
Small Organ (specify) ^[2]	Р	Р	Р		Р		Р	Р	Р		
Neonatal Cephalic										<u> </u>	
Adult Cephalic											
Cardiac ^[3]	Р	Р	Р		P		Р	P	P		
Peripheral Vascular	Р	Р	Р		Р		Р	Р	P		<u> </u>
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Thoracic/Pleural (specify) [4]			<u> </u>				<u> </u>	ļ			
Other ^[4]								<u></u>			
Exam Type, Means of Access									<u> </u>		
Transesophageal				<u> </u>				<u> </u>			
Transrectal		٠.	<u> </u>				<u> </u>	<u> </u>			
Transvaginal											
Transuretheral											<u> </u>
Intraoperative (specify)[5]	P	Р	P		Р		Р	P	P		<u> </u>
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes:	[1] Abdon	oinal includ	ac GVN a	nd Urological
INDLES.	THEADDON	uman muanm	PS 15 IN 20	111 1.11 1.11 1.11 1.11

- [2] Small organ includes breast, testes, thyroid.
- [3] Cardiac is Adult and Pediatric.
- [4] For detection of fluid and pleural motion/sliding;
- [5] Other use includes Urology/Prostate
- [*] Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD.
- [*] Coded Pulse is for digitally encoded harmonics.

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	Division of Reproductive, Abdominal and
Per 21 CFR 801.109)	Radiological Devices

510(k) Number <u>K091374</u>

Prescription User (Per 21 CFR 801.109)

GE Compact Ultrasound with 3S-RS Transducer

LOGIQ i, LOGIQ e, Vivid e

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

					Mode	of Ope	eration				
Clinical Application Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler			Harmonic Imaging	Coded Pulse	Other
Ophthalmic											
Fetal / Obstetrics	Р	P	Р	Р	Р	Р	Р	Р	Р	Р	
Abdominal ^[1]	P	Р	Р	Р	Р	Р	Р	Р	P	Р	
Pediatric	Р	Р	P	Р	Р	Р	Р	Р	Р	Р	
Small Organ (specify)			ļ								<u> </u>
Neonatal Cephalic					, , , , , , , , , , , , , , , , , , ,						
Adult Cephalic	Р	Р	P	Р	P	Р	Р	Р	Р_	P	
Cardiac ^[3]	Р	Р	.p	Р	P	Р	P	P	Р	P	<u> </u>
Peripheral Vascular			<u> </u>								ļ
Musculo-skeletal Conventional											ļ
Musculo-skeletal Superficial					ļ						<u> </u>
Thoracic/Pleural (specify)[4]	N	N	N	N	N	N	N	N	N	N	ļ
Other ^[5]	Р	Р	P	Р	P	Р	Р	Р	Р	Р	
Exam Type, Means of Access		ļ	<u> </u>			<u> </u>					<u> </u>
Transesophageal			<u> </u>	<u> </u>	<u> </u>	ļ					
Transrectal		<u> </u>				ļ			<u> </u>	<u> </u>	<u> </u>
Transvaginal											
Transuretheral		ļ							<u> </u>		ļ
Intraoperative (specify)				1		ļ	ļ	· .		<u> </u>	<u> </u>
Intraoperative Neurological					<u> </u>	<u> </u>				ļ <u>.</u>	<u> </u>
Intravascular							<u> </u>				
Laparoscopic]									

Notes:	[1]	Abdominal	includes	GYN	and	Urological
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- [2] Small organ includes breast, testes, thyroid.
- [3] Cardiac is Adult and Pediatric.
- [4] For detection of fluid and pleural motion/sliding;
- [5] Other use includes Urology/Prostate
- [*] Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD. [*] Coded Pulse is for digitally encoded harmonics.

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	Division of Reproductive, Abdominal and
Prescription User (Per 21 CFR 801.109)	Radiological Devices 510(k) Number 15 (291374

GE Compact Ultrasound with 6S-RS Transducer

LOGIQ i, LOGIQ e, Vivid e

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation										
Clinical Application Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler		Harmonic Imaging	Coded Pulse	Other
Ophthalmic											
Fetal / Obstetrics											ļ
Abdomina(^[1]	Р	Р	P	Р	P	Р	Р	Р	Р	Р	
Pediatric	Р_	P	P	P	Р	P	Р	P	Р_	Р	
Small Organ (specify)[2]											
Neonatal Cephalic	P	Р	Р	Р	Р	Р	Р	P	Р	Р	
Adult Cephalic •	Р	Р	Р	Р	P	Р	Р	Р	Р	P	
Cardiac ^[3]	Р	P	P	Р	Р	Р	Р	P	P	Р	
Peripheral Vascular											
Musculo-skeletal Conventional										<u> </u>	
Musculo-skeletal Superficial											
Thoracic/Pleural (specify) [4]											
Other ^[5]	P	Р	Р	Р	P	Р	P	Р	Р	Р	
Exam Type, Means of Access								<u> </u>			
Transesophageal	_					·					
Transrectal											
Transvaginal											
Transuretheral								<u> </u>			
Intraoperative (specify)[5]						_					
Intraoperative Neurological							<u> </u>				<u> </u>
Intravascular											
Laparoscopic	. =				<u> </u>		<u> </u>	<u> </u>		<u> </u>	<u> </u>

Motes: [1] Appointment includes O 114 and Olotogic	Notes: [Abdominal includes GYN and Urological
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- [2] Small organ includes breast, testes, thyroid.
- [3] Cardiac is Adult and Pediatric.
- [4] For detection of fluid and pleural motion/sliding;
- [5] Other use includes Urology/Prostate
- [*] Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD.
- [*] Coded Pulse is for digitally encoded harmonics.

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Prescription User (Per 21 CFR 801.109)	Division of Reproductive, Abdominal and				
	Radiological Devices 510(k) Number				
	510(k) Number KO91374				

GE Compact Ultrasound with P2D Transducer

LOGIQ i, LOGIQ e, Vivid e

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

		· -··			···		 			
	Mode of Operation									
Clinical Application Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppier		Harmonic Imaging	Coded Pulse	Other
Ophthalmic										
Fetal / Obstetrics										
Abdominal ^[1]			<u> </u>							
Pediatric										
Small Organ (specify) ^[2]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac ^[3]				P						
Peripheral Vascular				P						
Musculo-skeletal Conventional					<u></u>					
Musculo-skeletal Superficial			<u> </u>							
Thoracic/Pleural (specify)[4]			<u>.</u>							
Other ^[5]										
Exam Type, Means of Access			ļ							
Transesophageal										
Transrectal							<u> </u>			
Transvaginal										
Transuretheral										
Intraoperative (specify)[5]										
Intraoperative Neurological										
Intravascular					,					
Laparoscopic										

Notes:	[1]	Abdominal	includes	GYN	and	Urological
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- [2] Small organ includes breast, testes, thyroid.
- [3] Cardiac is Adult and Pediatric.
- [4] For detection of fluid and pleural motion/sliding;
- [5] Other use includes Urology/Prostate
- [*] Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD.
- [*] Coded Pulse is for digitally encoded harmonics.

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